

## REMARKS

### I. Status Summary

Claims 1, 26 and 27 are currently pending in the subject patent application. Claims 1, 26 and 27 have been examined by the Patent Office and currently stand rejected.

The Patent Office maintains that claims 1 and 27 do not have priority to the filing date of Australian Patent Application No. 2003/901425 (hereinafter "the Priority Document"), and the effective filing date of claims 1 and 27 is the filing date of the instant application, or March 23, 2004.

Claims 1, 26 and 27 have been rejected under 35 U.S.C. §112, first paragraph, upon the contention that the claims fail to comply with the written description requirement.

The Patent Office has rejected claims 1, 26 and 27 under 35 U.S.C. §103(a) upon the contention that the claims are unpatentable over Claes et al. (2001) *Am J of Human Genet* 68:1327-1332 (hereinafter referred to as "Claes et al.").

Claims 1, 26 and 27 have been canceled. New claims 28-30 have been added. Support for new claims 28-30 can be found throughout the specification as filed, including particularly at page 5, lines 1-30; page 6, lines 22-33; and page 37, line 22, through page 42, line 13. Further support can be found in Figure 1; Table 3; and in original claims 1 through 4. No new matter has been added.

Reconsideration of the application based on the arguments set forth herein is respectfully requested.

### II. Telephone Interview Summary

A telephone interview was scheduled and conducted on October 6, 2009. Participating in the Interview were Examiner Stephen Kapushoc and applicants' counsel of record, Arles A. Taylor, Jr. and Leon Legleiter. Applicants wish to express their sincere appreciation for Examiner Kapushoc's time and consideration in participating in the Telephone Interview.

The pending claims were discussed, and were proposed new claims. The cited Claes et al. reference was also discussed. It is believed that an agreement was

reached as to the patentability of new claims 28-30 as presented herein above. Accordingly, applicants submit new claims 28-30 formally herein.

II. Response to the Objection to the Priority Claim

The Patent Office maintains that claims 1 and 27 are not properly supported by the Priority Document because the element of testing for an alteration in a regulatory region is not disclosed in the Priority Document.

Without acquiescing to the contentions of the Patent Office with regard to claims 1 and 27, claims 1 and 27 have been canceled. Withdrawal of this objection as moot is therefore respectfully requested.

III. Response to the 35 U.S.C. §112, First Paragraph, Written Description Rejection

Claims 1, 26 and 27 have been rejected under 35 U.S.C. §112, first paragraph, upon the contention that the claims fail to comply with the written description requirement. The Patent Office contends that claims 1, 26 and 27 contain new matter.

Without acquiescing to the contentions of the Patent Office, claims 1, 26 and 27 have been canceled. Thus, applicants respectfully request that the rejection of claims 1, 26 and 27 under 35 U.S.C. §112, first paragraph, be withdrawn at this time, as moot.

IV. Response to the 35 U.S.C. §103(a) Rejection in view of Claes *et al.*

The Patent Office has rejected claims 1, 26 and 27 under 35 U.S.C. §103(a) upon the contention that the claims are unpatentable over Claes *et al.* Particularly, the Patent Office asserts that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the explicit teachings of Claes *et al.* to perform an analysis of a patient suspected of SMEI that meets all of the required limitations of the rejected claims.

Without acquiescing to the contentions of the Patent Office, claims 1, 26 and 27 have been canceled. Accordingly, applicants respectfully request that the rejection of claims 1, 26 and 27 under 35 U.S.C. § 103(a) over Claes *et al.* be withdrawn as moot. Additionally, it is respectfully submitted that new claims 28-30 are patentably distinguished over Claes *et al.* in accordance with applicants' understanding of the

agreements reached in the above-described Telephone Interview. A Notice of Allowance is also respectfully requested.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any other fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

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